



December 19, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, #1061
Rockville, Maryland 20852

Re: Proposed Rule: Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed.
67 Fed. Reg., 65448, October 24, 2002.

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation on drug patent listing requirements and 30-month stays. This regulation has the potential to begin closing loopholes that delay access to low-cost generics. This is important for AARP's 35 million members age 50 and over, and for all Americans who are struggling to pay escalating prices for brand name prescription drugs.

We particularly appreciate President Bush's remarks in announcing this proposal, that brand name manufacturers "deserve the fair rewards" of their research but "do not have the right to keep generic drugs off the market for frivolous reasons." We agree and believe that permitting only one 30-month stay per drug product per abbreviated new drug application (ANDA) and prohibiting 30-month stays for patents on process, packaging, metabolites, and intermediates is a good start toward reaching that proper balance.

However, we are concerned that, without additional legislation, the proposed regulation may not succeed in achieving that proper balance and closing loopholes that have inappropriately kept generics off the market.

- Language in the proposed regulation is open to multiple interpretations. We appreciate that this is a highly technical issue. However, we are struck by the disparity of opinions among experts in the field on exactly what the proposed regulation would do. The preamble and text are written with heavy use of words and phrases that, while terms of art in the field, are apparently ambiguous even to experts. This ambiguity invites misinterpretation and litigation that could delay or prevent the regulation from having its intended effect. The proposal seems to be a prime example of the "lost in translation" problem cited by the HHS Secretary's Advisory Committee on Regulatory Reform in its draft report.

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We urge you to work to ensure that the language is clear and unambiguous to all members of the wide audience that is concerned about this issue.

- The regulation does not state unequivocally that only one 30-month stay per drug per ANDA is allowed. This is stated in the summary and preamble. It may be the intent of language in the last paragraph of the proposed regulation text. However, it is not stated clearly in the actual proposed regulation text. An unambiguous statement in the actual final regulation text that brand-name manufacturers may be granted only one 30-month stay per drug per ANDA would help ensure that this is universally understood and enforceable.

We urge you to state clearly and unequivocally in the final regulation text that only one 30-month stay per drug per ANDA is allowed.

- There is no provision for challenging FDA decisions on whether to list individual patents in the Orange Book. There has been bipartisan support for allowing manufacturers to challenge these determinations in court. There also has been concern that court challenges could pose a burden of their own. Absent the right to challenge determinations in federal court, alternatives such as a mediation system or a special dedicated court could provide the necessary checks and balances while limiting costs and delays.

We urge you to provide necessary checks and balances and to consider alternative dispute resolution systems for timely and efficient challenges to FDA patent determinations.

- Limiting stays is not enough to ensure timely market access for generics. Brand name manufacturers could still file new patents on a drug during a 30-month stay and sue for patent infringement after a 30-month stay has concluded. There is bipartisan concern in Congress about the potential for such multiple patent filings to continue to block market access for generics. There also is bipartisan support for legislation to allow patents to be listed in the Orange Book for only a limited time after brand-name product approval and to bar brand-makers from suing later than 45 days after a generic application, regardless of whether a patent is eligible for a 30-month stay.

We urge you to limit the time after brand-name product approval in which additional patents may be listed in the Orange Book and to limit the time after a generic application that a brand-maker may sue, regardless of whether a patent is eligible for a 30-month stay -- through regulation if possible; if not, then through legislation.

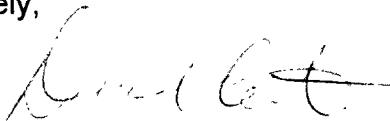
Page 3

- FDA's statutory authority is subject to challenge. A legal challenge asserting that FDA does not have authority to take the steps in this proposed regulation is likely. Regardless of the merits of such litigation, it could cause long delays in enactment of this regulation and closing of loopholes that are inappropriately keeping generics off of the market.

We urge the Administration to support legislation that explicitly gives FDA the necessary authority to close these and other loopholes that have been used to delay consumer access to low-cost generic drugs.

We appreciate the opportunity to comment on the proposed regulation. If you have any questions or need additional information, please contact Paul Cotton of the Federal Affairs staff at (202) 434-3770.

Sincerely,

A handwritten signature in black ink, appearing to read "David M. Certner", written over a light gray horizontal line.

David M. Certner
Director
Federal Affairs